

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION

HENRY STANLEY JR., Derivatively on Behalf )  
of Cardinal Health, Inc., )  
Plaintiff, ) Case No.: 12-CV-00482  
v. )  
COLLEEN F. ARNOLD, GEORGE S. ) JURY TRIAL DEMANDED  
BARRETT, GLENN A. BRITT, CARRIE S. )  
COX, CALVIN DARDEN, BRUCE L. )  
DOWNEY, JOHN F. FINN, GREGORY B. )  
KENNY, DAVID P. KING, RICHARD C. )  
NOTEBAERT, DAVID W. RAISBECK, JEAN G.)  
SPAULDING, DAVE BING, R. KERRY )  
CLARK, GEORGE H. CONRADES, PHILIP L. )  
FRANCIS, JOHN F. HAVENS, J. MICHAEL )  
LOSH, JOHN B. MCCOY, MICHAEL )  
O'HALLERAN, MATTHEW D. WALTER, and )  
ROBERT D. WALTER, )  
Defendants, )  
and )  
CARDINAL HEALTH, INC., )  
Nominal Defendant. )

**VERIFIED SHARHOLDER DERIVATIVE COMPLAINT**

For Plaintiff Henry Stanley Jr.'s ("Plaintiff") Verified Shareholder Derivative Complaint, Plaintiff alleges the following upon personal knowledge as to himself, and upon information and belief as to all other allegations, based upon his attorneys' investigation of information pertinent to the claims herein alleged:<sup>1</sup>

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<sup>1</sup> Plaintiff has principally derived the facts alleged herein from sources including United States Securities and Exchange Commission ("SEC") filings, newspaper articles, websites, and filings

## **NATURE OF THE ACTION**

1. This is a shareholder derivative action brought pursuant to Federal Rule of Civil Procedure 23.1 on behalf of nominal defendant Cardinal Health, Inc. (“Cardinal Health” or the “Company”), against the current members of the Company’s Board of Directors (the “Board”) and certain former directors and officers. Plaintiff seeks injunctive and other relief against defendants for breaches of fiduciary duties owed to Cardinal Health arising out of the Company’s repeated violations of federal regulations that required the Company to implement a system to detect and prevent the diversion of controlled substances into the illegal market. These breaches of fiduciary duties have substantially injured and will continue to substantially injure the Company.

2. Cardinal Health is one of the largest wholesale pharmaceutical drug distributors in the United States. Through its distribution facilities, the Company distributes, among other things, controlled substances to its customers throughout the country.

3. Federal regulations require distributors of Schedule I and Schedule II controlled substances – those with a high potential for abuse – to register with the Drug Enforcement Agency (the “DEA”) and maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. Moreover, distributors must design and operate systems to disclose suspicious orders of controlled substances and notify the DEA of such orders. If a registrant fails to comply with these responsibilities, the DEA may suspend the party’s registration by issuing an immediate suspension order (“ISO”) in instances where the DEA believes that the registrant’s continued operation would pose “an imminent danger to the public health and safety.”

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in connection with *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C. 2012), including briefs, supporting affidavits, and a Memorandum Opinion issued on March 7, 2012.

4. In late 2007, the DEA issued ISOs to three of Cardinal Health's drug distribution facilities, including its drug distribution facility located in Lakeland, Florida (the "Lakeland Facility"). The DEA issued the ISOs based on investigations that disclosed, among other things, that the Lakeland Facility failed to maintain effective controls against the diversion of controlled substances into the illicit market. Not long after the issuance of the three ISOs, in January 2008, the DEA issued an order instructing Cardinal Health to show cause as to why the DEA should not revoke one of its facilities' certificates of registration, based on the facility's failure to maintain effective controls against diversion.

5. As a result of the conduct that was the subject of the ISOs and order to show cause, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA on September 29, 2008 (the "MOA"), in which Cardinal Health explicitly agreed, among other things, to maintain a compliance program designed to detect and prevent the diversion of controlled substances, as required under federal and DEA regulations. The MOA was signed by Director Defendant R. Kerry Clark ("Clark"), Cardinal Health's former Chairman and Chief Executive Officer ("CEO"), on behalf of the Company. Additionally, Cardinal Health agreed to pay a civil fine of \$34 million, which, at the time, was the *largest* fine in United States history associated with a DEA registration suspension.

6. Despite Cardinal Health's previous and repeated violations of federal regulations and the Company's entry into the MOA, the Company nevertheless did not implement an adequate system to detect and prevent diversion. Rather, not long after entering into the MOA, and after the DEA repeatedly notified Cardinal Health of its need to exercise greater diligence at its Lakeland Facility to detect suspicious activity by its customers, the DEA issued an ISO regarding the Lakeland Facility on February 2, 2012. Once again, the DEA concluded that the

Lakeland Facility's continued registration posed an imminent danger to public health and safety.

7. As a result of the Company's continuous failure to comply with federal and DEA regulations – and violation of the terms of the MOA – Cardinal Health now potentially faces substantial fines, as well as loss of business, damage to the Company's reputation, and significant attorneys' fees. Indeed, as Jon Giacomin ("Giacomin"), President of U.S. Pharmaceutical Distribution for Cardinal Health, has stated, as a result of the 2012 Lakeland Facility ISO, Cardinal Health's business reputation will be significantly tarnished, and customers will take their entire pharmaceutical business away from Cardinal Health. He anticipates that the delays will cause some of Cardinal Health's customers to leave Cardinal Health permanently for other distributors, as occurred following the 2007 Lakeland Facility ISO, and that the 2012 ISO will likely have an even *greater* impact than the 2007 ISO did.

8. As current or past directors and officers of Cardinal Health, each of the Director Defendants (defined herein) owe and have owed Cardinal Health and its shareholders the fiduciary duties of loyalty and due care in the management and administration of the Company's affairs. As more fully described herein, the Director Defendants caused and/or allowed Cardinal Health to knowingly engage in repeated and persistent violations of federal regulations, despite the presence of numerous red flags. As a result of these actions, Cardinal Health and the Director Defendants have profited substantially, with the Company making significant profits as a result.

9. As detailed herein, the current and former directors and officers of the Company caused and/or allowed Cardinal Health to disregard its obligations under federal regulations for a substantial period of time, despite knowing that Cardinal Health was violating the law and faces substantial monetary fines and damage in connection with its misconduct. The wrongdoing

detailed herein was not misconduct perpetrated at the bottom levels of the Company hidden from the view of senior managers and directors. The Director Defendants' actions (and inaction) were serious and substantial violations of their fiduciary duties to the Company's shareholders.

### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action under and pursuant to 28 U.S.C. § 1332(a) because this action is an action for, *inter alia*, damages in excess of \$75,000, exclusive of interest and costs, and there is complete diversity of citizenship.

11. This action is not a collusive one to confer jurisdiction on a Court of the United States that it would not otherwise have.

12. Venue is proper in this District because Cardinal Health is incorporated in this District and headquartered here.

### **THE PARTIES**

#### ***Plaintiff***

13. Plaintiff is an owner of Cardinal Health stock and was an owner of Cardinal Health stock at all times relevant to the Director Defendants' wrongful conduct alleged herein. Plaintiff is a resident of South Carolina.

#### ***Nominal Defendant***

14. Nominal Defendant Cardinal Health is an Ohio corporation and maintains its principal executive offices at 7000 Cardinal Place, Dublin, Ohio 43017. Cardinal Health is a \$103 billion health care services company that provides pharmaceuticals and medical products to more than 60,000 locations each day. Cardinal Health is a leading manufacturer of medical and surgical products, including gloves, surgical apparel and fluid management products. Additionally, the Company supports the growing diagnostic industry by supplying medical

products to clinical laboratories and operating the nation's largest network of radiopharmacies that dispense products to aid in the early diagnosis and treatment of disease. Cardinal Health's common stock is traded on the NYSE under the ticker symbol "CAH."

***The Director Defendants***

**Current Director Defendants**

15. Defendant Colleen F. Arnold ("Arnold") has served as a Cardinal Health director since August 2007. Arnold is a member of the Company's Nominating and Governance Committee (the "Governance Committee"). Arnold served on the Compensation Committee from 2007 until February 2009 and on the Audit Committee from February 2009 until February 2010. Upon information and belief, Arnold is a resident of Maine.

16. Defendant George S. Barrett ("Barrett") has served as a Cardinal Health director and as Chairman of the Board and CEO since August 2009. Barrett has been Chair of the Company's Executive Committee since August 2009. Upon information and belief, Barrett is a resident of Pennsylvania.

17. Defendant Glenn A. Britt ("Britt") has served as a Cardinal Health director since October 2009. Britt has been a member of the Company's Audit Committee since 2009 and has been Chair since October 2009. Britt is also a member of the Executive Committee. Upon information and belief, Britt is a resident of Connecticut.

18. Defendant Carrie S. Cox ("Cox") has served as a Cardinal Health director since December 2009. Cox has been a member of the Company's Audit Committee since 2009. Upon information and belief, Cox is a resident of Florida.

19. Defendant Calvin Darden ("Darden") has served as a Cardinal Health director since 2005. Darden has been a member of the Company's Compensation Committee since 2005.

Upon information and belief, Darden is a resident of Georgia.

20. Defendant Bruce L. Downey (“Downey”) has served as a Cardinal Health director since August 2009. Downey has been a member of the Company’s Audit Committee since August 2009. Upon information and belief, Downey is a resident of Virginia.

21. Defendant John F. Finn (“Finn”) has served as a Cardinal Health director since 1994. Finn has been a member of the Company’s Audit Committee since at least 2004 and served as Chair from at least 2005 until 2008 and then again in 2010. Finn also has been a member of the Governance Committee since at least 2004 and a member of the Executive Committee from at least 2004 until November 2007 and then again since August 2009. Upon information and belief, Finn is a resident of Michigan.

22. Defendant Gregory B. Kenny (“Kenny”) has served as a Cardinal Health director since August 2007. Kenny is Chair of the Company’s Compensation Committee and has served on the Compensation Committee since 2007. Kenny has also been a member of the Governance Committee since February 2009, the Executive Committee since 2008, and the Audit Committee from 2006 until November 2007. Upon information and belief, Kenny is a resident of Ohio.

23. Defendant David P. King (“King”) has served as a Cardinal Health director since September 2011. King has been a member of the Company’s Audit Committee since November 2011. Upon information and belief, King is a resident of North Carolina.

24. Defendant Richard C. Notebaert (“Notebaert”) has served as a Cardinal Health director since 1999. Notebaert has been a member of the Company’s Compensation Committee from at least 2004 until December 2008 and served as Chair from 2006 until December 2008. Notebaert has also been a member of the Governance Committee from at least 2006 until December 2008 and the Executive Committee since at least 2006. Upon information and belief,

Notebaert is a resident of Florida.

25. Defendant David W. Raisbeck (“Raisbeck”) has served as a Cardinal Health director since 2002. Raisbeck has been Chair of the Company’s Governance Committee since July 2009 and has been a member of the Compensation Committee since August 2009, the Audit Committee from at least 2004 until 2008, and the Executive Committee since July 2009. Upon information and belief, Raisbeck is a resident of Minnesota.

26. Defendant Jean G. Spaulding, M.D. (“Spaulding”) has served as a Cardinal Health director since 2002. Spaulding has been a member of the Company’s Compensation Committee since at least 2004. Upon information and belief, Spaulding is a resident of North Carolina.

### **Former Director Defendants**

27. Defendant Dave Bing (“Bing”) served as a Cardinal Health director from 2000 until his retirement in November 2005. Bing was a member of the Company’s Audit Committee at the time of his retirement. Upon information and belief, Bing is a resident of Michigan.

28. Defendant Clark served as a Cardinal Health director from April 2006 until he retired in August 2009. Clark was the Company’s President and CEO since April 2006. During his time at the Company, Clark served on the Executive Committee since 2006 and was Chair since 2006. Upon information and belief, Clark is a resident of Ohio.

29. Defendant George H. Conrades (“Conrades”) served as a Cardinal Health director from April 1999 until his term as a director expired in November 2008. During his time at the Company, Conrades served on the Audit Committee since at least 2004, the Executive Committee since at least 2004, and the Governance Committee since at least 2004 and was Chair from at least 2004 until 2006. Upon information and belief, Conrades is a resident of Florida.

30. Defendant Philip L. Francis (“Francis”) served as a Cardinal Health director from November 2006 until he resigned from the Board in August 2009. During his time at the Company, Francis was a member of the Audit Committee since 2006. Upon information and belief, Francis is a resident of Arizona.

31. Defendant John F. Havens (“Havens”) served as a Cardinal Health director from 1979 until November 2006. Havens was a member of the Company’s Governance Committee and the Compensation Committee since at least 2004. Upon information and belief, Havens is a resident of Ohio.

32. Defendant J. Michael Losh (“Losh”) served as a Cardinal Health director from 1996 until he resigned from the Board in August 2009. Losh was the Company’s Chief Financial Officer (“CFO”), on an interim basis, from July 2004 to May 2005. While at the Company, Losh was a member of the Audit Committee from at least 2006 until 2009 and served as Chair since 2007, and also served on the Governance Committee and the Executive Committee since 2007. Upon information and belief, Losh is a resident of Michigan.

33. Defendant John B. McCoy (“McCoy”) served as a Cardinal Health director from 1987 until his retirement in July 2009. During his time at the Company, McCoy served on the Executive Committee since at least 2004, the Compensation Committee since at least 2004 and was Chair since 2006, and the Governance Committee since at least 2004 and served as Chair from at least 2004 until 2005. Upon information and belief, McCoy is a resident of Florida.

34. Defendant Michael D. O’Halleran (“O’Halleran”) served as a Cardinal Health director from April 1999 until he resigned from the Board in August 2009. While at the Company, O’Halleran was a member of the Audit Committee since at least 2004. Upon information and belief, O’Halleran is a resident of Illinois.

35. Defendant Matthew D. Walter (“M. Walter”) served as a Cardinal Health director from May 2002 until January 2008. Upon information and belief, M. Walter is a resident of Ohio.

36. Defendant Robert D. Walter (“R. Walter”) served as a Cardinal Health director from when he founded the Company in 1971, as Cardinal Foods, until his term as a director expired in November 2008. R. Walter served as the Company’s Executive Chairman of the Board from April 2006 until November 8, 2007 and as Chairman and CEO from 1971 to April 2006. From November 2007 until June 2008, R. Walter served as Executive Director. While at the Company, R. Walter was a member of the Company’s Executive Committee since at least 2004 and served as Chair in 2006. Upon information and belief, R. Walter is a resident of Ohio.

37. The defendants referred to in paragraphs 14 to 25 are collectively referred to hereinafter as the “Current Director Defendants.”

38. The defendants referred to in paragraphs 14 to 35 are collectively referred to hereinafter as the “Director Defendants.”

### **FACTUAL BACKGROUND**

#### ***Applicable Federal Regulations***

39. The Controlled Substances Act (“CSA”) creates restrictions on the manufacture, distribution, and dispensing of legally produced controlled substances, and the CSA authorizes the DEA to enforce the provisions of the CSA. Among other things, the DEA is authorized to establish a registration program for manufacturers, distributors, and dispensers of controlled substances to prevent the diversion of legally produced controlled substances into the illicit market. Accordingly, entities that seek to produce or distribute controlled substances must register with the DEA.

40. Pursuant to the CSA, distributors of Schedule I or Schedule II drugs, which have a high potential for abuse, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” Moreover, distributors that supply controlled substances to pharmacies must “design and operate a system to disclose to the registrant suspicious orders of controlled substances,” and disclose those suspicious orders to the DEA.<sup>2</sup>

41. Under the CSA, the DEA may revoke or suspend an entity’s registration for, *inter alia*, committing “such acts as would render his registration . . . inconsistent with the public interest.” Typically, before suspending or revoking a registration, the DEA must issue an order to show cause, outlining its basis for the proceedings. However, in instances where the DEA has reason to believe that a registrant’s continued operation would pose “an imminent danger to the public health or safety,” the DEA may suspend the entity’s registration immediately by issuing an ISO pursuant to Section 824(d) of the CSA. An ISO will remain in effect “until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.”

#### ***Cardinal Health and the Lakeland Facility***

42. Cardinal Health is one of the largest wholesale pharmaceutical drug distributors in the United States. The Company was founded in 1971 and has been distributing pharmaceuticals since 1979.

43. According to its website, Cardinal Health provides pharmaceuticals and medical products to more than 60,000 locations each day. The Company is also a leading manufacturer of medical and surgical products, including gloves, surgical apparel and fluid management

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<sup>2</sup> Pursuant to 21 C.F.R. 1301.74, “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

products. Cardinal Health is ranked number nineteen on the Fortune 500, and employs more than 30,000 people worldwide.

44. Cardinal Health currently has approximately twenty-five drug distribution facilities that are registered with the DEA. The Lakeland Facility, located at 2045 Interstate Drive, Lakeland, Florida 33805, distributes Schedule II, III, IV, and V controlled substances. According to Giacomin, the Lakeland Facility “distributes a very large volume of prescription drugs and controlled substances in Florida. . . . The Lakeland facility is thus one of the largest wholesale prescription drug distributors in Florida.”

***Previous ISOs and Orders to Show Cause Directed to Cardinal Health***

45. Based on findings from DEA investigations, between November 28, 2007 and December 7, 2007, the DEA issued three ISOs to Cardinal Health in connection with three facilities whose continued registration with the DEA constituted an imminent danger to public health and safety.

46. On November 28, 2007, the DEA issued an ISO to Cardinal Health in connection with its distribution center in Auburn, Washington (the “Auburn Facility”), immediately suspending the facility’s Certificate of Registration because its continued registration constituted “an imminent danger to public health and safety.” According to the ISO, the Auburn Facility repeatedly “distributed unusually large amounts of hydrocodone” to Horen’s Drugstore, Inc. (“Horen’s Drugstore”)—distributing 600,000 dosage units of hydrocodone to Horen’s Drugstore from March 2007 through September 2007—and “*disregard[ed] the clear indications that Horen’s Drugstore was engaged in the diversion of controlled substances[.]*” (Emphasis added).

47. Horen’s Drugstore was Cardinal Health’s largest purchaser of combination hydrocodone products in 2007, and according to the ISO, the drugstore was “a pharmacy

engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law.” The DEA found that Cardinal Health “failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels,” and concluded that its continued registration with the DEA constituted “an imminent danger to the public health and safety.”

48. On December 5, 2007, the DEA issued an ISO to Cardinal Health regarding the Lakeland Facility (the “2007 ISO”). Pursuant to the 2007 ISO, Cardinal Health was notified of the immediate suspension of the Lakeland Facility’s Certificate of Registration because its “continued registration constitute[d] an imminent danger to public health and safety.”

49. The 2007 ISO detailed how, from August 2005 through October 2007, Cardinal Health failed to maintain effective controls against the diversion of hydrocodone into other than legitimate medical, scientific and industrial channels, in violation of the CSA:

*From August 2005 through October 2007, Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.*

Many of Respondent’s largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. . . .

(Emphasis added).

50. According to the 2007 ISO, Cardinal Health distributed hydrocodone to various pharmacies, even though Cardinal Health knew that many of the orders placed by the pharmacies were of an unusual size and were “suspicious” as defined in 21 C.F.R. § 1301.74(b). The ISO explained that Cardinal Health repeatedly supplied the pharmacies “*with excessive amounts of hydrocodone* despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers’ association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies.” (Emphasis added).

51. For example, Cardinal Health distributed 1,213,200 dosage units to Q-R-G, Inc. over the course of February to June 2006. Moreover, the Company distributed 1,148,100 dosage units to United Prescription Services, Inc. from July to October 2006.

52. The 2007 ISO further detailed that on September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for Cardinal Health, sent an email to the DEA’s E-Commerce Section, stating that Cardinal Health discontinued its sales of controlled substances to thirteen Internet pharmacies, including RKR Holdings, Inc. (“RKR Holdings”). Nevertheless, from September 1, 2006, to January 31, 2007, Cardinal Health distributed 393,600 dosage units of combination hydrocodone products to RKR Holdings.

53. In the 2007 ISO, the DEA concluded that Cardinal Health “failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety[,]” and “Respondent’s continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to

divert large quantities of controlled substances.”

54. Two days after the 2007 ISO was issued, on December 7, 2007, the DEA issued an ISO to Cardinal Health because, from January 2005 to August 2007, its distribution center in Swedesboro, New Jersey (the “Swedesboro Facility”) “distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.” The ISO stated that “[s]ome of Respondent’s largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice.”

55. As described in the Swedesboro Facility ISO, “Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled substances. . . . *Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels.*” (Emphasis added). The DEA ordered the immediate suspension of the Swedesboro Facility’s Certificate of Registration because its continued registration constituted “an imminent danger to the public health and safety.”

56. Following the issuance of the three ISOs to Cardinal Health, on January 30, 2008, the DEA issued an Order to Show Cause that provided Cardinal Health an opportunity to show cause as to why the DEA should not revoke the Certificate of Registration assigned to the Company’s Stafford, Texas distribution center (the “Stafford Facility”). According to the Order to Show Cause, the Company distributed approximately 1,381,500 dosage units of hydrocodone

to Richmond Pharmacy from January 2, 2007 to September 11, 2007, which significantly exceeded, on a daily basis, the daily limit set by Cardinal Health for its retail pharmacy customers. Moreover, the Company shipped 12,000 dosage units of hydrocodone to Richmond Pharmacy three days after being notified that Richmond Pharmacy surrendered its DEA registration and was no longer authorized to order or dispense controlled substances.

57. Cardinal Health's policy was to limit a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units per day. Nevertheless, Cardinal Health frequently distributed hydrocodone in quantities that greatly exceeded that limit. For example, the Company distributed 66,000 dosage units of hydrocodone to Richmond Pharmacy on September 4, 2007; 48,000 dosage units on September 10, 2007; and 24,000 dosage units on September 11, 2007.

58. The Order to Show Cause stated:

Registrant [Cardinal Health] distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substances – Registrant did not have sufficient policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.

*Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances.*

(Emphasis added).

59. Moreover, the Order to Show Cause set forth that:

Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled

substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.

The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

60. Following the three ISOs and the Order to Show Cause, the DEA and Cardinal Health entered into the MOA on September 29, 2008. The MOA discussed the three ISOs and the Order to Show Cause, as well as the DEA's allegations that "Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities" located in McDonough, Georgia (the "McDonough Facility"), Valencia, California (the "Valencia Facility"), and Denver, Colorado (the "Denver Facility").

61. Pursuant to the MOA, Cardinal Health agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Specifically:

This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

62. The MOA detailed additional obligations for Cardinal Health, including, *inter*

*alia*, that:

- (a) “On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol”;
- (b) “Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b)”;
- (c) “Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement”;
- (d) “Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal’s obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b)[]”; and
- (e) “Cardinal’s policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys’ Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal’s customers for alleged violations or activities related to the Covered Conduct[.]”

63. Additionally, Cardinal Health agreed that:

[W]ithin 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures

established under Cardinal's compliance program.

64. Moreover, Cardinal Health agreed to pay, pursuant to 21 U.S.C. § 842(c), a civil fine of \$34 million for violations of 21 U.S.C. § 842(a)(5), to settle claims for civil penalties for failing to report suspicious orders of controlled substances.

65. The MOA was signed by, among others, Director Defendant Clark, on behalf of Cardinal Health.

66. The following day, on September 30, 2008, the United States Department of Justice ("DOJ") and Cardinal Health entered into a settlement agreement which, among other things, specifically set out what portions of the \$34 million civil penalty were allocated to which Cardinal Health distribution facilities.

67. Specifically, the \$34 million was payable as follows: (i) \$3 million for conduct alleged to have taken place within the District of New Jersey (the Swedesboro Facility); (ii) \$16 million for conduct alleged to have taken place within the Middle District of Florida (the Lakeland Facility); (iii) \$8 million for conduct alleged to have taken place within the Southern District of Texas (the Stafford Facility); (iv) \$3.5 million for conduct alleged to have taken place within the Western District of Washington (the Auburn Facility); (v) \$1 million for conduct alleged to have taken place within the District of Colorado (the Denver Facility); (vi) \$1.5 million for conduct alleged to have taken place within the Northern District of Georgia (the McDonough Facility); and (vii) \$1 million for conduct alleged to have taken place within the Central District of California (the Valencia Facility).

68. Notably, the largest portion of the fine was attributable to the Lakeland Facility.

69. This agreement was signed by, among others, Director Defendant Clark on behalf of Cardinal Health.

70. In total, the DEA had reason to believe that seven of Cardinal Health's twenty-seven then-registered distribution centers were not adhering to their obligations as registrants. This was nearly *twenty-five percent* of Cardinal Health's registered distribution centers.

71. The Lakeland Facility 2007 ISO was lifted on October 2, 2008, which was nearly ten months after the issuance of the ISO on December 5, 2007.

***Cardinal Health's Subsequent Violations of the CSA***

72. Between October 2008 and December 2011, the DEA investigated the Lakeland Facility's distribution of oxycodone to its top four Florida retail customers: (i) Holiday CVS, L.L.C., CVS #00219 in Sanford ("CVS 219"); (ii) Holiday CVS, L.L.C., CVS # 05195 in Sanford ("CVS 5195"); (iii) Caremed Health Corporation, Brooks Pharmacy in Bonita Springs ("Caremed"); and (iv) Gulf Coast Pharmacy in Fort Myers ("Gulf Coast").

73. According to a declaration of Joseph Rannazzisi, a Deputy Assistant Administrator for the DEA's Office of Diversion Control (the "Rannazzisi Declaration," attached hereto as Exhibit A),<sup>3</sup> submitted in connection with Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction (the "Opposition Brief") filed in *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C. 2012), between October 2008 and December 2011, among other things, the DEA: conducted compliance reviews at Cardinal Health's distribution centers; interviewed Cardinal Health employees; met with representatives of Cardinal Health; issued administrative inspection warrants ("AIW") to CVS 219, CVS 5195, Caremed, and Gulf Coast; and investigated CVS 219, CVS 5195, Caremed, and Gulf Coast. As a result of the investigations, Caremed and Gulf Coast subsequently voluntarily surrendered their DEA registrations for cause.

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<sup>3</sup> The facts set forth in the Rannazzisi Declaration are incorporated herein by reference.

74. Additionally, the DEA issued an AIW to the Lakeland Facility on October 26, 2011. The AIW was issued to allow the DEA to “determine whether Cardinal Health has failed to report suspicious orders to DEA as required by 21 U.S.C. § 827(d)(1) and 21 CFR § 1301.74(b).” As set forth in an affidavit in support of the AIW, “In view of the foregoing circumstances the current inspection is necessary for the purpose of protecting the public health and safety. Sales of oxycodone by Cardinal Health represent an unusually large quantity of narcotic controlled substances to the average retail pharmacy.” In response to the AIW, Cardinal Health produced documents to the DEA.

75. Subsequently, on November 8, 2011, the DEA issued an administrative subpoena to Cardinal Health for information regarding its sales of oxycodone and other drugs, as well as its compliance mechanisms.

76. As detailed in the Rannazzisi Declaration, based on the DEA’s review of the documents produced by Cardinal Health, “the investigation at Cardinal Lakeland revealed a persistent failure to exercise due diligence to ensure that controlled substances were not being diverted.” The DEA concluded that, “over a period of approximately 3 years, November 2008 to December 2011, Cardinal’s anti-diversion controls were inadequate to meet their due diligence responsibilities.” This conclusion was based on, among other things, “evidence that Cardinal’s due diligence practices were inconsistent with both the 2008 MOA and Cardinal’s own policies the purpose of which was to reduce diversion.” During this time period, Cardinal Health’s top four Florida retailers were supplied approximately fifty times the amount of oxycodone compared to the average Florida retailer that Cardinal Health services.

77. As set forth in the Rannazzisi Declaration, Cardinal Health, among other things:

- Regularly exceeded the distribution thresholds it established for itself.

From April 2009 to August 2011, Cardinal Health disregarded its own oxycodone thresholds for its top four Florida retailers at least forty-four times, at times by up to tens of thousands of pills.

- Failed to follow its own suspicious order monitoring policies, which required a customer site visit to investigate potential diversion once Cardinal Health attached a “red flag” to a particular customer. A number of sales should have triggered a “red flag” under Cardinal Health’s operating procedures.
- Failed to conduct site visits for its retail chain pharmacy customers, thus failing to maintain effective controls to prevent diversion of controlled substances. A number of indicators of diversion could have been ascertained by conducting a site visit.
- Reported only low numbers of suspicious orders (failing almost altogether to report any suspicious orders at CVS 219, CVS 5195, Caremed, and Gulf Coast – only reporting *two* suspicious orders with respect to CVS 219, which occurred after the issuance of the AIW) and continued to sell controlled substances to certain customers after allegedly terminating those customers.

78. Details regarding the DEA’s investigations are also set forth in the declaration of Ruth A. Carter, a DEA Group Supervisor who served as the lead case agent assigned to the Lakeland Facility investigation, which was submitted in support of the Opposition Brief (the “Carter Declaration,” attached hereto as Exhibit B).<sup>4</sup>

79. According to the Carter Declaration, with respect to CVS 219:

- Had Cardinal Health conducted a site visit, it would have learned that, between January 1, 2010 and October 18, 2011, forty-two percent of oxycodone sales were in cash, which is an indicator of potential diversion under Cardinal Health’s own policy, “Potential

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<sup>4</sup> The facts set forth in the Carter Declaration are incorporated herein by reference.

Indicators of Diversion.” Fewer than seven percent of patients nationwide paid for their prescriptions with cash in 2010.

- Cardinal Health increased its monthly oxycodone distributions by approximately 832 percent from 2008 to 2009, and by sixty-three percent from 2009 to 2010. Moreover, CVS 219 purchased 1,802,100 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health’s own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales five times between November 25, 2009 and November 24, 2010, allowing CVS 219’s monthly allowance of dosage units to increase from 112,000 to 319,000 per month.

- Although Cardinal Health held sixty-eight shipments for further inquiry, fifty-three of those shipments were ultimately released (and of the fifteen withheld, eleven were duplicate orders).

- Cardinal Health only reported two suspicious orders to the DEA, and these were only reported *after* receiving the AIW.

- Cardinal Health never sent investigators to visit CVS 219.
- Cardinal Health’s failure to conduct a site visit evidenced its failure to “maintain effective controls against diversion,” as required under the CSA.

80. The Carter Declaration specifically outlined “what Cardinal knew or should have known” with respect to CVS 219, outlining numerous facts and concluding that, “[h]ad Cardinal conducted appropriate due diligence, there is reason to believe that it would have known that sales to CVS 219 posed a risk of diversion for illicit use.” Among other things:

- A site visit to CVS 219 would have revealed that a significant portion of

the pharmacy's oxycodone customers were not using the drug for legitimate purposes. For example, during an October 2011 DEA visit to CVS 219, the "pharmacist in charge" told the DEA that "customers often requested certain brands of oxycodone using street slang" and "30 mg oxycodone was the pharmacy's fastest moving controlled substance." Moreover, "approximately every third car that came through the drive-thru lane had prescriptions for oxycodone or hydrocodone."

- Despite the high volume of oxycodone and exponentially increasing orders, Cardinal Health never conducted a site visit that examined CVS 219's practices or procedures, choosing instead to rely on the pharmacy's own internal controls.
- Based on the DEA's review of Cardinal Health's files, the Company failed to investigate the practices at CVS 219.

81. Moreover, according to the Carter Declaration, with respect to CVS 5195:

- Had Cardinal Health conducted a site visit, it would have learned that fifty-eight percent of oxycodone sales were in cash between January 1, 2010 and October 18, 2011.
- Cardinal Health increased its monthly oxycodone distributions by approximately 793 percent from 2008 to 2009, and by 748 percent from 2009 to 2010. Moreover, CVS 5195 purchased 1,210,400 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.
- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales four times between August 11, 2010 and November 24, 2010, allowing CVS 5195's monthly allowance of dosage units to increase from 27,000 to 177,700 dosage units.

- Although Cardinal Health held twenty-two shipments for further inquiry, all of those shipments were ultimately released.
- Cardinal Health did not make any suspicious order reports to the DEA regarding CVS 5195.
- Cardinal Health never had investigators conduct a site visit of CVS 5195.
- Cardinal Health’s failure to conduct a site visit evidenced its failure to “maintain effective controls against diversion,” as required under the CSA.

82. The Carter Declaration specifically described “what Cardinal knew or should have known” with respect to CVS 5195, outlining a number of facts and concluding that, “[h]ad Cardinal conducted appropriate due diligence, there is reason to believe that it would have known that sales to CVS 5195 posed a risk of diversion for illicit use.” Among other things:

- During a DEA visit to the pharmacy, the pharmacist in charge explained that she “set a daily limit on the number of oxycodone 30 milligram prescriptions the pharmacy would fill each day. She put the limit in place because, among other reasons, she wanted to ensure that the pharmacy had enough oxycodone 30 milligram to fill the prescriptions for ‘real pain patients.’” The same pharmacist “described the pharmacy’s oxycodone customers as ‘shady’ and admitted that some of the prescriptions were probably not legitimate.”
- Despite the high volume of oxycodone and exponentially increasing orders, Cardinal Health never conducted a site visit that examined CVS 5195’s practices or procedures, choosing instead to rely on the pharmacy’s internal controls.
- Based on the DEA’s review of Cardinal Health’s files, the Company failed to investigate the practices at CVS 5195.

83. According to the Carter Declaration, with respect to Gulf Coast:

- Forty percent of oxycodone sales were in cash as of April 30, 2009.
- Cardinal Health increased its monthly oxycodone distributions by approximately 549 percent from 2008 to 2009, and by 404 percent from 2009 to 2010. Moreover, Gulf Coast purchased 2,063,100 dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health's own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales eleven times between April 13, 2009 and May 26, 2010, allowing Gulf Coast's monthly allowance of dosage units to increase from 20,000 to 314,400.
- Although Cardinal Health held sixty-one shipments for further inquiry, fifty-two of those shipments were ultimately released, and of the nine orders not shipped, almost half were duplicate orders.
- Cardinal Health did not make any suspicious order reports to the DEA regarding Gulf Coast.
- Cardinal Health conducted five site visits to Gulf Coast between August 2008 and February 2011. One of those visits resulted in an assessment of "High Risk of Diversion." A second visit resulted in an assessment of "Medium Risk of Diversion." Nevertheless, Cardinal Health did not contact the DEA regarding these findings, and indeed, shortly after reaching these conclusions, substantially *increased* its monthly volumes of oxycodone to Gulf Coast. The "High Risk of Diversion" assessment was made on October 5, 2011. The report from the site visit indicated, "I have requested permission to contact DEA to resolve this issue." However, Cardinal Health did not contact the DEA, and on November 24, 2010, the Company adjusted its monthly volumes of oxycodone to Gulf Coast from 141,000 to

207,200. Moreover, the “Medium Risk of Diversion” assessment was made on February 17, 2011. Nevertheless, Cardinal Health increased Gulf Coast’s order threshold from 207,200 to 245,000 on April 26, 2011; from 245,000 to 265,000 on April 27, 2011; and from 265,000 to 317,000 on May 26, 2011. These increases constituted a sixty-five percent increase in Cardinal Health’s authorized shipment volumes of oxycodone.

- On November 4, 2011, Gulf Coast voluntarily surrendered its DEA registration for cause.

84. According to the Carter Declaration, with respect to Caremed:

- Forty percent of oxycodone sales were in cash as of September 21, 2011.
- Cardinal Health increased its monthly oxycodone distributions by approximately 1020 percent from 2008 to 2009, and by 213 percent from 2009 to 2010. Moreover, Caremed purchased 1.1 million dosage units from Cardinal Health in 2011. These amounts surpassed the amount of the drug purchased by Cardinal Health’s own pharmacies and in the State of Florida.

- Cardinal Health adjusted its monthly allowance threshold for oxycodone sales nine times between April 14, 2010 and May 26, 2011, allowing Caremed’s monthly allowance of dosage units to increase from 26,000 to 158,300 dosage units.

- Although Cardinal Health held fifty-four shipments for further inquiry, forty-seven of those shipments were ultimately released, and of the seven orders Cardinal Health did not ship, three were duplicate orders.

- Cardinal Health did not make any suspicious order reports to the DEA regarding Caremed.

- In response to the AIW, Cardinal Health conducted three site visits to

Caremed between May 4, 2010 and September 21, 2011. After one of these investigations, a Cardinal Health employee recommended that the Company hold oxycodone shipments to Caremed at their current volume. Nevertheless, Cardinal Health increased the orders two times in the following four months, constituting a fifty-seven percent increase. The third site visit resulted in a conclusion of “High Risk of Diversion.”

- Caremed voluntarily surrendered its DEA registration for cause on October 18, 2011.

85. Based on its investigations, the DEA issued a second ISO regarding the Lakeland Facility on February 2, 2012 (the “2012 ISO”). The 2012 ISO provided that “[d]espite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).”

86. The 2012 ISO stated that “[s]ince at least 2009, Cardinal’s largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and outside the usual course of professional practice.”

87. According to the 2012 ISO, from January 1, 2008 to December 31, 2011, Cardinal Health’s sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units, and the “egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal’s Florida retail pharmacies[.]” Specifically, from January 1, 2008 to December 31, 2011, Cardinal Health sold: (i) over 5 million dosage units of oxycodone to its top customer,

CVS 219; (ii) approximately 3.4 million dosage units of oxycodone to Gulf Coast; (iii) approximately 2.2 million dosage units of oxycodone to CVS 5195; and (iv) approximately 2.1 million dosage units of oxycodone to Caremed. The volumes of oxycodone in dosage units shipped to these customers is summarized in the chart below:

Customer	2008 Volume	2009 Volume	2010 Volume	2011 Volume	2009 to 2011 Percentage Change	Total
<b>CVS 219</b>	135,000	1,258,600	2,048,100	1,802,100	43%	5,243,800
<b>CVS 5195</b>	11,700	104,500	885,900	1,210,400	1058%	2,212,500
<b>Gulf Coast</b>	32,820	213,100	1,073,540	2,063,100	868%	3,382,560
<b>Caremed</b>	20,700	231,740	724,500	1,097,300	374%	2,074,240
<b>Total Per Year</b>	200,220	1,807,940	4,732,040	6,172,900	241%	12,913,100

88. The 2012 ISO stated that, “[n]otwithstanding the large quantities of controlled substances ordered by Cardinal’s top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal’s failure to conduct due diligence of its retail pharmacy chain customers.” The ISO continued: “Cardinal failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. § 1301.74(b). In addition, Cardinal’s conduct described herein violated the provisions of the Administrative Memorandum of Agreement.”

89. As set forth in the 2012 ISO, “Cardinal’s continued registration is inconsistent with the public interest[,]” and “continued registration while the[] proceedings are pending constitutes an imminent danger to the public health and safety.”

90. According to the declaration of Michele M. Leonhart, Administrator of the DEA who issued the four ISOs discussed herein, which was submitted in support of the Opposition

Brief (the “Leonhart Declaration,” attached hereto as Exhibit C),<sup>5</sup> “Cardinal’s prior compliance problems, particularly those at Cardinal Lakeland, played a significant role in my conclusion to issue the February 2, 2012 ISO. I found that Cardinal Lakeland had failed to maintain adequate diversion controls, had violated the terms of its 2008 MOA, and posed an imminent danger to public health and safety.”

91. Under a section of her declaration titled “Cardinal’s History of Inadequate Controls Against Unlawful Diversion,” Leonhart explained, among other things:

Between November 28, 2007, and December 7, 2007, I issued ISOs suspending distributions at three Cardinal facilities – including Cardinal Lakeland. At the time, I concluded that the three facilities posed an imminent danger to public health or safety based on a DEA investigation revealing that Cardinal Lakeland “failed to maintain effective controls against diversion.” On January 30, 2008, DEA also issued an Order to Show Cause to revoke the registration of Cardinal’s Stafford, Texas facility based on the failure to maintain effective controls against diversion. . . .

In addition to the four Cardinal distribution facilities described above, I also had reason to conclude that Cardinal “failed to maintain effective controls against the diversion of controlled substances” at three other facilities.

On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA. I approved the terms of the 2008 MOA between Cardinal and DEA. The purpose of the 2008 MOA was to establish mechanisms to ensure all Cardinal distribution facilities comply with the CSA.

(Citations omitted).

92. The Leonhart Declaration continues:

DEA’s recent investigation indicated that Cardinal Lakeland had been distributing excessive quantities of oxycodone to its top Florida retail pharmacy customers. DEA previously suspended Cardinal Lakeland because of its failure to maintain adequate safeguards against diversion, a conclusion DEA reached after an investigation into Cardinal Lakeland’s distribution of hydrocodone to internet pharmacies. *Although the drugs and the end customers were different, the common thread was Cardinal Lakeland’s inadequate anti-diversion measures. The results of the recent investigation strongly indicated to me that, contrary to its*

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<sup>5</sup> The facts set forth in the Leonhart Declaration are incorporated herein by reference.

*promises in the 2008 MOA, Cardinal had not maintained adequate anti-diversion measures at its Lakeland facility.*

(Emphasis added).

93. According to Leonhart, “Cardinal Lakeland sold high volumes of oxycodone to these CVS stores despite all the warning signs, leading me to conclude that Cardinal’s Lakeland facility had failed in its obligation to identify, report, and act upon the suspicious nature of the orders placed by these stores. This failure violated the terms of the MOA and the CSA.” Furthermore, “*Cardinal Lakeland was on notice of its obligation to maintain adequate anti-diversion controls.* DEA advised Cardinal Lakeland of its obligations through the MOA and through ongoing communications with Cardinal Lakeland, in which it provided guidance concerning warning signs that could indicate ongoing diversion. Nevertheless, Cardinal Lakeland continued to supply these customers despite clear warning signs. . . . [H]ad Cardinal Lakeland taken basic steps to investigate their activities, it would had detected serious problems with its top four customers.” (Emphasis added). Moreover, “the disturbing pattern of sales to all four pharmacies over an extended time period gave me reason to believe that Cardinal Lakeland did not have adequate anti-diversion controls in place with regard to its sales to its more than 5,200 other retail customers.”

94. On February 3, 2012, Cardinal Health filed a complaint and an application for a temporary restraining order (“TRO”) with respect to the 2012 ISO. *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C. 2012). After a hearing that took place on February 3, 2012, at which counsel for the government was not present, the Court granted Cardinal Health’s request for a TRO. Cardinal Health subsequently filed a Motion for Preliminary Injunction on February 6, 2012, which the Court denied on February 29, 2012. The Company filed a notice of appeal on February 29, 2012, and filed an emergency motion for injunction pending appeal on

March 2, 2012, which was denied on March 16, 2012.

95. On May 15, 2012, Cardinal Health announced that it agreed to a settlement with the DEA to resolve the ongoing litigation with respect to the 2012 ISO. Pursuant to the settlement, Cardinal Health agreed to a two-year suspension of the Lakeland Facility's DEA registration to ship controlled medicines from the facility. Cardinal Health also agreed, as it did in 2008, to improve its anti-diversion procedures.

#### ***Harm to the Company***

96. As a result of the repeated disregard and violation of the CSA and applicable laws, Cardinal Health has suffered substantial harm.

97. Due to the conduct that took place from 2005 to 2008, Cardinal Health has already paid a \$34 million civil fine, which was, at the time, the *largest* fine in United States history associated with a DEA registration suspension. Of that \$34 million fine, \$16 million—a little less than half of the fine—was attributable to the conduct that took place at the Lakeland Facility.

98. Not only did the Company suffer the \$34 million fine, but according to Giacomin, President of U.S. Pharmaceutical Distribution for Cardinal Health,<sup>6</sup> after the 2007 ISOs, “[m]any of Cardinal Health’s customers relayed their concerns . . . about the disruptions in service they experienced as a result of those ISOs. . . . [M]any of those customers left Cardinal Health and have not returned.”

99. Moreover, “Cardinal Health suffered significant revenue losses as a result of the

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<sup>6</sup> Cardinal Health submitted three Giacomin declarations (the “Giacomin Declarations”) in *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185 (D.D.C. 2012). The first declaration was submitted on February 3, 2012, in connection with the Company’s application for a TRO. The other declarations were submitted on February 6, 2012 and February 13, 2012, in connection with the Company’s Motion for Preliminary Injunction.

December 5, 2007 suspension of the Lakeland facility.” Giacomin explained that delays in shipments due to the ISO “caused some customers to leave Cardinal Health for other distributors.” Moreover, on August 7, 2008, Current Director Defendant Barrett, Cardinal Health’s CEO, publicly disclosed to investors on an earnings call that, at that time, “Cardinal Health estimated that the suspensions of the Lakeland, Auburn, Swedesboro, and Stafford facilities, and related remedial measures, had *caused Cardinal Health to lose ‘roughly \$1 billion of lost sales’ on an annualized basis.*” (Emphasis added).

100. According to Giacomin, as a result of the 2007 ISO, some customers that stayed with Cardinal Health decreased the amounts of purchases they made from the Company and increased purchases from other suppliers, and even after the Lakeland Facility resumed shipping in October 2008, “average purchases by the remaining customers remained depressed.” The Company has estimated that “*just one portion of these losses*—decreased sales to retail independent pharmacies that remained with Cardinal Health—*amounted to approximately \$100 million.*” (Emphasis added).

101. According to a May 10, 2012 *Bloomberg* article titled “Cardinal Health Set for DEA Showdown Over Painkiller Sales Ban,” “[f]rom the DEA’s first facility suspension on Nov. 28, 2007, to Oct. 29, 2008, when the company reported first-quarter earnings after settling with the agency, Cardinal shares fell 40 percent to \$25.21 from \$42.26.”

102. With respect to the 2012 ISO, the Giacomin Declarations provide that “[t]he rerouting of controlled substances to other distribution centers [other than the Lakeland Facility] will require Cardinal Health to expend substantial effort and resources.” Moreover, “[i]t is anticipated that some of Cardinal Health’s Florida customers experiencing service delays will leave Cardinal Health for other distributors and Cardinal Health’s business reputation will be

significantly tarnished as customers come to view Cardinal Health as unreliable. . . . [T]hese customers will take their entire pharmaceutical business away from Cardinal Health. Their perceptions of Cardinal Health's reliability, moreover, may carry over to potential customers as well."

103. Giacomin has also expressed that "[t]he inability to distribute pharmaceuticals in the Florida market could have severe consequences for Cardinal Health's entire pharmaceutical business. Indeed, many national chain customers, who cannot receive timely shipments for their controlled substances in Florida, will choose to take their national accounts to other distributors. As a result, DEA's ISO poses a risk to Cardinal Health's national business in pharmaceuticals." The Company anticipates that the "delays will cause some of Cardinal Health's customers to leave Cardinal Health permanently for other distributors, as occurred following the 2007 ISO of the Lakeland facility. These harms cannot later be cured."

104. Giacomin has concluded that "[i]t is likely that an ISO of the Lakeland distribution center today *would have an even greater impact than the December 5, 2007 ISO did*. During the period in which the Lakeland facility's registration was suspended as a result of the December 5, 2007 ISO, Cardinal Health's principal competitors, McKesson and AmerisourceBergen, faced disruptions in their distributions to Florida as well. Absent those disruptions, the losses to Cardinal Health as a result of the December 5, 2007 ISO likely would have been even greater." (Emphasis added).

105. According to a May 15, 2012 article in *The Wall Street Journal*, "Cardinal has said that shipping the controlled medicines from longer distances—and the legal costs associated with the DEA case—added about \$4 million in costs during its most recent quarter."

106. As a result of the 2012 ISO, the Company has and will continue to suffer

significant harm and incur substantial costs, including potential fines, attorneys' fees, loss of business, and reputational harm.

**DERIVATIVE ALLEGATIONS**

107. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

108. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered by the Company because of the breaches of fiduciary duties by the Director Defendants.

109. Plaintiff will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights, and has retained counsel experienced in litigating actions of this type.

110. Plaintiff is an owner of Cardinal Health stock and was an owner of Cardinal Health stock at all times relevant to the Director Defendants' wrongful conduct alleged herein.

**DEMAND IS EXCUSED**

111. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

112. Cardinal Health is incorporated in Ohio, and, thus, Ohio corporation law governs the issue of whether Plaintiff was required to make a demand on the Company's Board to institute this case before filing this Complaint. Making a demand is considered futile under Ohio law when the plaintiff can show that the directors' minds are closed to argument and that they cannot properly exercise their business judgment in determining whether the suit should be filed. A plaintiff has to point to facts that show that the presumed ability of the directors to make unbiased, independent business judgments about whether it would be in the corporation's best

interests to file the action does not exist in this case. Demand is presumptively futile where the directors are antagonistic, adversely interested, or involved in the transactions attacked.

113. Plaintiff has not made any demand on the Cardinal Health Board to institute an action against itself for the breaches of fiduciary duties as alleged herein because such demand would be a futile and useless act. As discussed herein, the Board members cannot properly exercise their business judgment in determining whether the suit should be filed, and the Director Defendants are antagonistic, adversely interested, and/or involved in the transactions attacked herein, as they face a substantial likelihood of liability for their role in Cardinal Health's improper conduct.

114. The Board currently consists of the following twelve individuals: Current Director Defendants Arnold, Barrett, Britt, Cox, Darden, Downey, Finn, Kenny, King, Notebaert, Raisbeck, and Spaulding.

115. Each of the Current Director Defendants was a member of the Board during the time period in which the wrongdoing discussed herein occurred. Moreover, a majority of the Current Director Defendants were Board members at the time the Company entered into the MOA – specifically, Current Director Defendants Arnold, Darden, Finn, Kenny, Notebaert, Raisbeck, and Spaulding.

116. Each of the Board members was aware of, or should have been aware of, numerous red flags regarding the Company's violations of federal regulations. Specifically, as discussed above, Cardinal Health received the three ISOs from the DEA between November 28, 2007 and December 7, 2007, and received an Order to Show Cause on January 30, 2008. Further, the Company entered into the MOA, signed by the Company's CEO, which described the violations at seven drug distribution centers, and in which Cardinal Health explicitly agreed

to maintain a compliance program designed to detect and prevent the diversion of controlled substances. As a result of the ISOs and Order to Show Cause, the Company was forced to pay \$34 million in civil fines. Further, the DEA advised Cardinal Health of its obligations through the MOA and through ongoing communications with the Company, in which it provided guidance concerning warning signs that could indicate ongoing diversion. Moreover, the DEA issued the AIW to the Lakeland Facility on October 26, 2011 to “determine whether Cardinal Health has failed to report suspicious orders to DEA as required by 21 U.S.C. § 827(d)(1) and 21 CFR § 1301.74(b). . . . Sales of oxycodone by Cardinal Health represent an unusually large quantity of narcotic controlled substances to the average retail pharmacy.”

117. Thus, despite clearly being placed on notice of Cardinal Health’s responsibilities and its repeated failure to detect and prevent diversion, the Director Defendants disregarded their fiduciary duties to the Company when, under their direction, the Company continued to, *inter alia*: disregard federal regulations, the MOA, and the Company’s own practices; supply customers with controlled substances despite clear warning signs of diversion; not conduct due diligence; and not report suspicious orders to the DEA.

118. The Director Defendants knowingly and consciously presided over the Company’s systematic violations of the CSA and other applicable regulations. Cardinal Health’s unique history of non-compliance with these laws and regulations, the previous issuance of ISOs and an Order to Show Cause, and the Company’s entry into the MOA (signed by the CEO) and payment of the \$34 million fine, render it impossible for the Board to claim ignorance concerning compliance failures. Through the MOA, the Company specifically agreed to implement a system to detect and prevent diversion and comply with the CSA and DEA regulations. To the extent any of the Director Defendants claims not to have actual knowledge

of the repeated violations of federal regulations taking place within Cardinal Health, such lack of knowledge could only be the product of willful blindness that constitutes bad faith breach of their fiduciary duties.

119. Defendants were, moreover, required to act upon information to protect the Company from continued legal violations being committed. Rather than doing so, the Director Defendants, in violation of their legal obligations, consciously ignored the information presented to them and about which they were otherwise made aware concerning the Company's extensive legal violations. As a result, the Current Director Defendants face a substantial likelihood of liability for their conduct and, therefore, demand is excused.

120. Additionally, each member of the Board is required to comply with the Company's Standards of Business Conduct. The first standard is to “[a]ct with integrity and in compliance with the law.” The Standards of Business Conduct specifically discuss “[a]nti-diversion compliance,” and explain that “Cardinal Health is committed to maintaining the integrity of the supply chain by developing and maintaining processes to help guard against diversion. We maintain ‘know your customer’ policies and procedures to validate that products we ship are sold in accordance with legal and contract requirements and are received by customers for their legitimate use.”

121. As discussed herein, each member of the Board has failed to comply with the Company's Standards of Business Conduct, specifically with respect to its requirements to act in compliance with the law and to develop and maintain processes to guard against diversion. Each of the Board members permitted individuals at all levels of the Company to engage in the misconduct discussed above. Accordingly, the Board members have breached their fiduciary duties to the Company, and as a result, the Company has been severely damaged and faces

substantial continued damage. Therefore, the Current Director Defendants each face a substantial likelihood of liability for their breaches of fiduciary duties and any demand upon them is futile.

122. Moreover, at various points during the relevant period, Current Director Defendants Arnold, Britt, Cox, Downey, Finn, Kenny, King, and Raisbeck (a majority of the Board) served as members of the Company's Audit Committee. Pursuant to the Audit Committee's Charter:

The Audit Committee is appointed by the Board of Directors (the "Board") of Cardinal Health, Inc. (the "Company") to assist the Board in monitoring (1) the integrity of the Company's financial statements, (2) the Company's ethics and compliance program, (3) the independent auditor's qualifications and independence, (4) the Company's processes for assessing and managing risk, (5) the performance of the Company's corporate audit function and independent auditors, and (6) the compliance by the Company with legal and regulatory requirements.

123. Among other things, the Audit Committee is required to "[o]btain reports from the Chief Legal and Compliance Officer at least annually regarding the implementation and effectiveness of the Company's ethics and compliance program, including compliance with applicable legal requirements and the Company's Standards of Business Conduct by the Company and its subsidiary/foreign affiliated entities." Moreover, the Audit Committee must "[e]stablish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters or other ethical matters including a process that allows for direct communication to the Audit Committee or their designee of any such issues."

124. Current Director Defendants Arnold, Britt, Cox, Downey, Finn, Kenny, King, and Raisbeck breached their fiduciary duties because the Audit Committee permitted the Company to

repeatedly violate the laws and regulations as discussed above, and failed to act in good faith to address the violations complained of herein, despite the Audit Committee's responsibilities to, among other things, assist in the Company's compliance with legal and regulatory requirements, including the CSA and DEA regulations. Therefore, these Current Director Defendants face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile.

125. Furthermore, at various points during the relevant period, Current Director Defendants Arnold, Finn, Kenny, Notebaert, and Raisbeck served as members of the Company's Governance Committee. Pursuant to the Governance Committee's Charter, one of the purposes of the Governance Committee is to recommend to the Board a set of corporate governance principles and perform a leadership role in shaping and overseeing the Company's corporate governance. The duties and responsibilities of the Governance Committee include, *inter alia*:

Make recommendations to the Board concerning the structure, composition and functioning of the Board and its committees, including the reporting channels through which the Board receives information and the quality and timeliness of the information. . . .

Develop and recommend to the Board a set of corporate governance principles applicable to the Company and annually review and recommend changes to these principles, as appropriate. . . .

Perform such other duties and responsibilities as are consistent with the purpose of the Governance Committee and as the Board or the Governance Committee deems appropriate.

126. Current Director Defendants Arnold, Finn, Kenny, Notebaert, and Raisbeck breached their fiduciary duties because the Governance Committee permitted the Company to repeatedly violate the laws and regulations as discussed above, and failed to act in good faith to address the violations complained of herein, despite the fact that they were on notice of the Company's activities and the consequences thereof; their responsibilities to, among other things,

shape and oversee the Company's corporate governance; and their role regarding the reporting channels through which the Board receives information and the quality and timeliness of the information. Therefore, these Current Director Defendants face a substantial likelihood of liability for their breaches of fiduciary duties and any demand upon them is futile.

127. As Cardinal Health's CEO, Current Director Defendant Barrett has received and continues to receive substantial monetary compensation and other valuable benefits. For instance, for the Company's fiscal year 2011, Barrett received total compensation of \$10,214,206. By the Company's own admission, Barrett is not independent. Thus, Barrett lacks independence, rendering him incapable of partially considering a demand to commence and vigorously prosecute this action.

128. The Board's decision not to implement a system to detect and prevent diversion, and instead knowingly cause Cardinal Health to undertake violation of federal regulations, cannot be regarded as a valid exercise of business judgment. The Board affirmatively adopted, implemented, and condoned a business strategy based on the violations of law, and the Director Defendants have profited substantially as a result. Serious violations of federal law occurred systematically and at every level of the Company as a direct result of the Board's decision to embrace a policy of calculated legal violations as the Company's deliberate business strategy. The Board's decision not to carry out the responsibilities set forth in the CSA, DEA regulations, and the MOA, and instead cause Cardinal Health to violate the applicable regulations, is not a valid exercise of business judgment. The Director Defendants knew that the failure to comply with the regulations would result in severe penalties, and nevertheless chose not to bring a prompt halt to the improper conduct causing the non-compliance or seek to redress Cardinal Health for the serious damages it has and will continue to sustain. The magnitude and duration

of the wrongdoing, as alleged herein, and the magnitude of the damages caused as a result of the wrongdoing, reflect a lack of good faith on the part of the Director Defendants.

**COUNT I**  
**BREACH OF FIDUCIARY DUTIES AGAINST THE DIRECTOR DEFENDANTS**

129. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

130. Each of the Director Defendants, because of his or her positions as directors and officers of Cardinal Health, owes and has owed fiduciary duties to the Company and its shareholders in connection with the management and operations of the Company's business and operations.

131. To properly discharge these duties, the Director Defendants are and were required to, among other things:

- (a) manage, conduct, supervise, and direct the business affairs of Cardinal Health in accordance with best practices, applicable laws, rules, and regulations, and the terms of the MOA;
- (b) neither violate nor permit any officer, director, agent, or employee of Cardinal Health to violate applicable laws, rules, or regulations, or the terms of the MOA; and
- (c) remain informed as to the status of Cardinal Health's business practices and operations and upon receipt of notice of information of imprudent or unsound practices or operations, make a reasonable inquiry in connection therewith, and take steps to correct such practices or operations.

132. Moreover, each of the Director Defendants has and had a duty to Cardinal Health and its shareholders to establish and maintain adequate internal controls to ensure that the Company was operated in a prudent and lawful manner. The Director Defendants have and had

an affirmative obligation to install an internal control system to discover wrongdoing. Additionally, where red flags exist, the Director Defendants have an obligation to take affirmative steps to address such issues.

133. As detailed herein, the Director Defendants caused and/or allowed the Company to violate federal regulations, and failed to properly and adequately maintain a system of internal controls adequate to insure the Company's compliance with, among other things, federal regulations and the MOA, in violation of their fiduciary duties. The Director Defendants instituted a corporate culture that encouraged unlawful and irresponsible activity resulting in the loss and continued loss of significant amounts of money, loss of business, and irreparable damage to the Company's reputation.

134. As a result of the Director Defendants' wrongful conduct and actions, Cardinal Health has suffered and will continue to suffer significant damage.

135. All of the Director Defendants, individually and in concert, engaged in the aforementioned conduct in breach of their fiduciary duties to the Company and conspired to, and did, abuse the control vested in them by virtue of their high-level positions in the Company.

136. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, Cardinal Health engaged in unlawful activities causing substantial damage to the Company.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment as follows:

- A. Authorizing the maintenance of this action as a derivative action, with Plaintiff as derivative plaintiff;
- B. Declaring that the Director Defendants have violated their fiduciary duties to the

Company;

- C. Awarding against all of the Director Defendants and in favor of the Company the amount of damages sustained by the Company as a result of the Director Defendants' breaches of fiduciary duties;
- D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
- E. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff demands trial by jury on all claims asserted herein.

Dated: June 22, 2012

**MINNILLO & JENKINS, CO. LPA**

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